Participants:
EU: Stan van Belkum, M. T. Carrasco Benitez, Miguel Bley,
EFPIA: Andrew Marr
FDA: Greg Brolund (Rapporteur), Melissa Chapman, Bill Ridgely,
PhRMA: Bob Hizer
MHLW: Mihoko Okada, Tetsunari Kihira ,Hiroshi Yamamoto
JPMA: Tadao Akiyama, Hitoshi Asano, Harv Martens, Yuichi Nagoshi, Masatoshi Ozeki, Keiji Sawamukai, Tetsuro Shimokariya, Koichi Takahashi
Observer: Bob Kapitany (Canada), John Hems (IGPA)

The following are the agreements and discussion items from this meeting:
All parties agreed to the following:
1. The folder naming proposed in the agenda and in Appendix 6 (see table 6-1) is accepted.
2. The specification will not explicitly mention a maximum file size. We will continue to investigate possible file size limitations and incorporate appropriate language in the Step 4 document.

The follow are the recorded actions items:

	Action Item	Assigned to:	Due Date
1.	Work with Adobe to provide questions to JPMA and MHLW regarding large files and other PDF issues in Japan.	Harv Martens	Before the February meeting.
2.	Investigate the possibility of having Adobe organize a session at the February meeting to discuss Acrobat plug-in products with particular attention to the Japanese language versions of Acrobat.	Harv Martens	January 4,2002
3.	Revise the table "Understanding the operation attribute" and the cases that were provided in the agenda. Circulate the new version for comment.	Greg Brolund	December 21, 2001
4.	Each regulatory member will determine if they still have a need to have specific information in the PDF document information fields.	EU,FDA,MHLW ,Health Canada	Before the February meeting.
5.	Update Appendix 4 to include comments from Andrew; use the dash ("-") as a separator in file and folder names.	M. T. Carrasco Benitez	Jan 4, 2002
6.	Update the text associated with table 6-1 to indicate the location of the "index.xml" and checksum files for the xml instance.	Greg Brolund	Jan 15, 2002
7.	Update the eCTD specification as needed and distribute prior to the Feb. meeting	Greg Brolund	Jan 15, 2002
8.	Include wording in the eCTD specification to advise against the use of "node extensions".	Greg Brolund	Jan 15, 2002

	Action Item	Assigned to:	Due Date
9.	Provide an empty file folder template of the eCTD.	M. T. Carrasco Benitez	Jan 15, 2002
10.	Regulators will discuss options for page numbering when reports are split into multiple files for the eCTD.	EU,FDA,MHLW ,Health Canada	Before the February meeting.

The next ICH Steering Committee meeting is in Brussels the week of February 4-7, 2002